UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IMPAX LABORATORIES, INC., *Plaintiff,* v. ACTAVIS LABORATORIES FL, INC., AND ACTAVIS PHARMA INC., *Defendants.*	C.A. No. 15-6934 (SRC-CLW) (consolidated) **ORAL ARGUMENT REQUESTED** **HIGHLY CONFIDENTIAL** **FILED UNDER SEAL**

ACTAVIS'S OPENING BRIEF IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT OF NONINFRINGEMENT

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TABLE OF ABBREVIATIONS

Abbreviation	Description
Actavis's Products	The generic carbidopa/levodopa extended release capsules in four different dosage strengths, 23.75 mg/95 mg, 36.25 mg/145 mg, 48.75 mg/195 mg, and 61.25 mg/245 mg that are the subject of Actavis's ANDA No. 208522
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
Amiji Rpt.	Expert Report of Mansoor M. Amiji, Ph.D., R.Ph. Regarding Infringement of U.S. Patent Nos. 8,557,283, 9,089,608, and 9,463,246 dated May 19, 2017
ANDA	Abbreviated New Drug Application
Appel Decl.	Expert Declaration of Leah E. Appel, Ph.D. In Support of Actavis's Motion for Summary Judgment
AUC	area under curve
CD	carbidopa
C_{max}	maximum concentration
D.I. 56	Joint Claim Construction and Prehearing Statement
D.I. 93	Plaintiff Impax Laboratories, Inc.'s Revised Claim Construction Brief for U.S. Patent No. 8,377,474

Abbreviation	Description
D.I. 118	Opinion and Order Regarding Claim Construction
D.I. 123	Stipulation and Order Dismissing U.S. Patent Nos. 8,377,474; 8,454,998; and 9,089,607
ER	extended release
Ex. __	Exhibit to the Declaration of Brian Drummond In Support of Actavis's Motion for Summary Judgment
FDA	Food and Drug Administration
IR	immediate release
Jenner Decl.	Expert Declaration of Peter G. Jenner, Ph.D. In Support of Actavis's Motion for Summary Judgment
LD	levodopa
Nangia	U.S. Patent Application No. 2007/0148238
patents-in-suit	U.S. Patent Nos. 8,557,283; 9,089,608; 9,463,246; and 9,533,046
PK	pharmacokinetic
POSA	A person of ordinary skill in the art
PTO	United States Patent and Trademark Office
the '283 patent	Ex. 1, U.S. Patent No. 8,557,283
the '608 patent	Ex. 2, U.S. Patent No. 9,089,608

Abbreviation	Description
the ’246 patent	Ex. 3, U.S. Patent No. 9,463,246
the ’046 patent	Ex. 4, U.S. Patent No. 9,533,046
the ’474 patent	Ex. 5, U.S. Patent No. 8,377,474
the ’427 patent	Ex. 6, U.S. Patent No. 7,094,427 (no longer asserted)
the ’998 patent	U.S. Patent No. 8,454,998 (no longer asserted)
the ’607 patent	U.S. Patent No. 9,089,607 (no longer asserted)
Tr.	Deposition Transcript

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*Emphasis added unless otherwise noted.

Defendants Actavis Laboratories FL, Inc. and Actavis Pharma Inc. (collectively, "Actavis") submit this opening brief in support of their motion for summary judgment of noninfringement.

I. INTRODUCTION

This case arises from Actavis's submission of an ANDA for approval to market generic carbidopa/levodopa ("CD/LD") extended release capsules in four different dosage strengths (collectively, "Actavis's Products"). Plaintiff Impax Laboratories, Inc. ("Impax") markets the branded product, Rytary®, and has asserted claims for infringement based on Actavis's ANDA filing.

Impax alleges that Actavis will infringe the following 37 claims ("the asserted claims") of U.S. Patent Nos. 8,557,283 ("the '283 patent"), 9,089,608 ("the '608 patent"), 9,463,246 ("the '246 patent"), and 9,533,046 ("the '046 patent") (Exs. 1-4, collectively, "the patents-in-suit"):

Patent	Claims
'283	1, 2, 3, 5
'608	5, 8, 10, 13, 17, 18, 19, 21
'246	1, 9, 14, 17, 19, 21, 25, 26, 37, 40, 42, 44, 48, 49, 51, 53
'046	7, 12, 14, 16, 18, 20, 21, 30, 31

The asserted claims are generally directed to LD formulations having specific structural features and methods of using those formulations. There is significant overlap of the asserted claims for the purposes of analyzing noninfringement insofar as the asserted claims all require either that, (1) the formulation contain a carboxylic acid in a "distinct bead" from CD/LD; or (2) that the formulation provide a specific pharmacokinetic ("PK") profile. [redacted]

[redacted]

Accordingly, Actavis seeks summary judgment that its Products will not directly or indirectly infringe any of the asserted claims, either literally or under the doctrine of equivalents.

[redacted] The only question for the Court to resolve is a legal one: does the claim term "wherein the carboxylic acid of (c) is in a distinct bead from (a) or (b)" allow the bead containing carboxylic acid to also contain CD/LD? Actavis submits that the answer should be no, and consequently its Products cannot infringe any claim requiring a carboxylic acid in a "distinct bead."

[redacted] Again the only questions for the Court to resolve are legal ones: what is the meaning of the claim terms "maximum concentration of said profile" and "do not fluctuate more than 40% between 0.5 hours and 6 hours"? The proper understanding of these terms leads inevitably to a finding of non-infringement. Furthermore, even if the Court were to agree with Impax's construction of these terms, summary judgment of non-infringement would still be appropriate because there is no evidence that Actavis has the specific intent to induce infringement. In short, summary judgment on both issues should be granted.

II. FACTUAL BACKGROUND

A. Rytary®

Impax's product, called Rytary®, is an extended-release CD/LD capsule approved by the FDA in January 2015, for the treatment of Parkinson's disease. [redacted]

[redacted]

[redacted]

B. Actavis's Products

1. Physical Structure of Actavis's Products

[redacted]

[redacted]

[redacted]

2. **Pharmacokinetics of Actavis's Products**

[redacted]

[redacted]

[redacted]

III. LEGAL STANDARDS

A. Summary Judgment

Summary judgment shall be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." FED. R. CIV. P. 56(a); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In determining whether there is a dispute as to any material fact, all justifiable inferences are to be drawn in favor of the non-moving party. *Anderson*, 477 U.S. at 255.

The moving party bears the burden of establishing that no genuine issue of material fact remains. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). "[W]ith respect to an issue on which the nonmoving party bears the burden of proof ... the burden on the moving party may be discharged by 'showing'… that there is an absence of evidence to support the nonmoving party's case." *Id.* at 325. A party moving for noninfringement "may meet its initial responsibility either by providing evidence that would preclude a finding of infringement, or by showing that the evidence on file fails to establish a material issue of fact essential to the patentee's case." *Novartis Corp. v. Ben Venue Labs., Inc.*, 271 F.3d 1043, 1046 (Fed. Cir. 2001).

B. Infringement

"Determining whether a patent claim has been infringed requires a two-step process: First, the claim must be properly construed to determine its scope and meaning. Second, the

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[2] In an apparent attempt to force ANDA applicants to meet the limitations of the asserted claims rather than FDA's standard bioequivalence metrics, Impax submitted a Citizens Petition to FDA alleging that the metrics required to show bioequivalence, AUC and C_{max} "are insufficient to demonstrate both a rapid onset of effect and extended duration of effect" of Rytary®. (Ex. 20, at IMPAX00875753.) Impax specifically indicated that a proposed generic product may satisfy the bioequivalence standard notwithstanding that the product has a different time to onset of effect, variability of plasma concentration, and duration of effect than Rytary®. (*Id*. at IMPAX00875750.) To date, FDA has not adopted Impax's recommendation.

claim as properly construed must be compared to the accused device or process." *PC Connector Solution LLC v. SmartDisk Corp.*, 406 F.3d 1359, 1362 (Fed. Cir. 2005). Infringement can be shown literally or by the doctrine of equivalents. The ultimate burden of proof for showing infringement is upon the patentee. *Medtronic, Inc. v. Mirowski Family Ventures, LLC*, 134 S. Ct. 843, 849 (2014). Literal infringement requires that the accused product include each and every limitation of the claim, and "[i]f even one limitation of the patent claim is missing from the accused product, there is no infringement." *Mas-Hamilton Grpl. v. LaGard, Inc.*, 156 F.3d 1206, 1211 (Fed. Cir. 1998).

When literal infringement does not exist because an accused product does not meet a claim limitation exactly, in certain limited circumstances, infringement may be found under a judicially created doctrine called the "doctrine of equivalents." "Under this doctrine, a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." *Warner-Jenkinson Co., Inc. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 21 (1997).

An element in the accused product is equivalent to a claim limitation if the differences between the two are "insubstantial" to a POSA. *Id.* at 40. Insubstantiality may be determined by analyzing whether the accused product "performs substantially the same function in substantially the same way to obtain the same result" as the claim limitation. *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950).

C. Prosecution History Estoppel

The doctrine of equivalents is subject to the doctrine of prosecution history estoppel, which acts to limit infringement by otherwise equivalent products or processes. Prosecution history estoppel prevents the doctrine of equivalents from recapturing subject matter surrendered during prosecution. *Litton Sys., Inc. v. Honeywell, Inc.*, 140 F.3d 1449, 1458 (Fed. Cir. 1998). The inquiry is whether a competitor would reasonably believe that the applicant had surrendered the relevant subject matter. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1457 (Fed. Cir.

1998). The applicability of prosecution history estoppel is a legal question. *Id.* at 1460.

There are two types of prosecution history estoppel: amendment based and argument based. For amendment based prosecution history estoppel, when "the patentee originally claimed the subject matter alleged to infringe but then narrowed the claim in response to a rejection, he may not argue that the surrendered territory comprised unforeseen subject matter that should be deemed equivalent to the literal claims of the issued patent." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 733–34 (2002). Instead, "[b]y the amendment [the patentee] recognized and emphasized the difference between the two phrases[,] and [t]he difference which [the patentee] thus disclaimed must be regarded as material." *Id.* A narrowing amendment made to satisfy any requirement of the Patent Act, including amendments to avoid the prior art, may give rise to an estoppel on infringement by equivalents. *Id.* at 736. A narrowing amendment gives rise to a presumption that the patentee surrendered any subject matter between the amended claim as originally filed and claims allowed by the Patent and Trademark Office (PTO). *Id.* at 741.

In instances where the asserted claims were not amended during prosecution, prosecution history estoppel can still arise if the applicant made arguments or statements in responding to an examiner's rejection and those statements evidence a clear and unmistakable surrender of subject matter. *Allen Engineering Corp. v. Bartell Industries, Inc.*, 299 F.3d 1336, 1350 (Fed. Cir. 2002). "Arguments made to overcome prior art can equally evidence an admission sufficient to give rise to a finding of surrender," even "when the arguments are made in the absence of any claim amendment." *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 1481 (Fed. Cir. 1998).

IV. ACTAVIS'S PRODUCTS WILL NOT DIRECTLY INFRINGE OR INDUCE INFRINGEMENT OF ANY OF THE ASSERTED CLAIMS REQUIRING A PARTICULAR FORMULATION STRUCTURE

As an initial matter, all of the asserted claims of the '283, '246 and '046 patents are directed to methods of using particular formulations of CD/LD. Actavis will not administer its Products to patients and therefore cannot be liable for direct infringement of any claim of these

patents. Therefore, Impax's claims for these three patents are based on indirect infringement. In order to prove that Actavis indirectly infringes any claim, Impax must prove that Actavis induces or contributes to an act of direct infringement. *See Limelight Networks, Inc. v. Akamai Techs., Inc.*, 134 S. Ct. 2111, 2117 (2014). As discussed below, administration of Actavis's Products will not directly infringe the asserted claims, and therefore Actavis cannot be liable for indirect infringement. The other patent, the '608 patent, is not a method of use patent, but is instead directed to a formulation. As discussed below, Actavis's Products do not infringe the '608 patent.

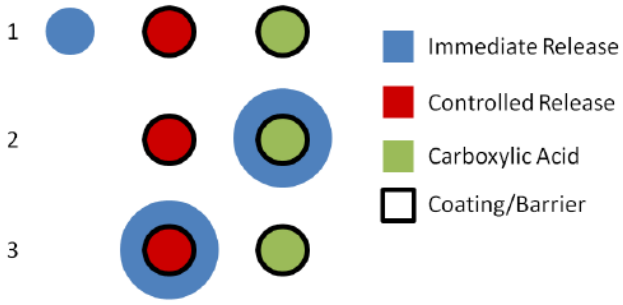
A. Claim Construction

The parties have provided the following competing proposed constructions for the term "wherein the carboxylic acid of (c) is in a distinct bead from (a) or (b)":

Term	Impax's Construction	Actavis's Construction
"wherein the carboxylic acid of (c) is in a distinct bead from (a) or (b)"	No construction necessary, plain and ordinary meaning.	Wherein the carboxylic acid of (c) is in a bead that is coated with an enteric polymer and physically separate from (a) or (b)

The Court has already construed a similar term from U.S. Patent No. 8,377,474 ("the '474 patent"), concluding that the claims containing the "distinct component" limitation require: "the carboxylic acid component must be freely separable from the controlled release and immediate release components prior to any final embedding of all elements in any constraining structure…" (D.I. 118 at 20.) The Court further explained that the "applicants clearly and unmistakably disclaimed coverage of formulations in which the carboxylic acid component is not freely separable from the controlled release and immediate release components…" (*Id.* at 26.)

To clarify its opinion, the Court provided a figure depicting what formulations would be covered by its construction:



In explaining the figure, the Court stated that it "need not reach the question of whether the second example (two kinds of beads or granules, with one being a combined carboxylic/IR or CR bead) would be allowable under this construction, because the prosecution history disclaimer surrenders all embodiments without a freely separable carboxylic acid component, which the second example lacks." (*Id.* at 23.) In light of the Court's opinion, [redacted] Impax agreed to dismiss all of the patents that required a "distinct component."[3] (D.I. 123.)

However, Impax maintains its assertion that Actavis's Products nonetheless infringe the '608 and '283 patents, which require a formulation wherein carboxylic acid is in a "distinct bead" rather than a "distinct component." This makes little sense, given that the term "distinct bead" is unquestionably ***narrower*** than the term "distinct component," a fact upon which Impax relied in arguing for its proposed construction of "distinct component" and which the Court acknowledged.[4] That Actavis's Products cannot infringe the "distinct bead" claims should therefore be self-evident.

Nevertheless, Impax contends that the plain and ordinary meaning of "wherein the

[3] Specifically, Impax agreed to dismiss U.S. Patent Nos. 8,377,474 ("the '474 patent"), 8,454,998 ("the '998 patent"), and 9,089,607 ("the '607 patent").

[4] In its review of the prosecution history of the '474 patent, the Court recognized that "distinct bead" was narrower than "distinct component," stating that "[a]s to the history of the amendments to claim 1, we see an initial, broadening of scope from 'distinct particle bead' to 'distinct component.'" (D.I. 118, fn 6 at 12; *see also* D.I. 93 at 19-20.)

carboxylic acid of (c) is in a distinct bead from" CD and LD, (*see, e.g.*, Ex. 1, '283 patent at claim 1), encompasses Actavis's Products, [redacted] First and foremost, the asserted claims do not require a distinct bead containing CD/LD, but a ***distinct bead containing a carboxylic acid***. Permitting the claims to cover formulations that include the carboxylic acid and CD/LD in a single bead, provided that there is a separate bead containing CD/LD, would render the requirement that the carboxylic acid be in a distinct bead from CD/LD meaningless. Impax's interpretation is entirely at odds with the plain and ordinary meaning, which is that the formulation contains a carboxylic acid in a distinct bead from the CD/LD, not the other way around.

This requirement that the carboxylic acid be in a bead with no CD/LD is consistent with the prosecution history, which is replete with representations of the importance of including a distinct carboxylic acid bead in the claimed formulation. As discussed at length in Actavis's prior claim construction submissions, and as recognized by the Court in its Claim Construction Opinion, Impax specifically disclaimed all formulations where the carboxylic acid was not in a separate component from CD/LD. During the prosecution of the '474 patent, the parent of the '283 and '608 patents, Impax specifically distinguished its claimed formulation over the Nangia

prior art reference that disclosed carboxylic acid in the same component as the CD/LD:

> Contrary to the Office's position, Nangia does not provide an indication of the need ***to create a separate carboxylic acid bead in the multiparticulate formulation***. The particles created by Nangia … were created in such a manner that the carboxylic acid as well as levodopa and a decarboxylase inhibit (e.g., carbidopa) were all present in a single particle or bead."
> …
> Nangia does not describe or suggest having a ***separate carboxylic acid*** bead in their formulation… There was simply no suggestion to separate the CD/LD from the carboxylic acid.

(Ex. 11, '474 File History at IMPAX00312254.) Impax viewed the separate carboxylic acid bead as critical to the invention because it created what Impax described as "bead-bead interactions":

> Applicants discovered the importance of ***bead-bead interactions between a bead containing levodopa/ decarboxylase inhibitor (e.g., carbidopa) and a separate bead containing a carboxylic acid*** on dissolution and plasma uptake that resulted in a favorable plasma profile for those suffering from Parkinson's disease.

(Ex. 11, '474 File History at IMPAX00312253.) Impax thus described its invention as "includ[ing] a distinct carboxylic acid bead separately coated with an enteric polymer together with the IR and CR beads or granules as recited in the claims." (Ex. 11, '474 File History at IMPAX00312330).

As the Court recognized, these statements confirmed that the proposed claims ***required*** a bead containing carboxylic acid that was freely separable and distinct from CD/LD beads. (D.I. 118 at 9 ("[T]he applicants distinguished Nangia as teaching formulations with the [CD/LD] and acid in the same bead, ***whereas [applicants] invented a formulation in which the carboxylic acid component is on a separate bead***").)

While a disclaimer made in a parent application may not always be applicable to the claims of a subsequent application, there is an "exception where an amendment to a related limitation in the parent application distinguishes prior art and thereby specifically disclaims a later (though differently worded) limitation in the continuation application." *Invitrogen Corp. v.*

Clontech Labs., Inc., 429 F.3d 1052, 1078 (Fed. Cir. 2005); *see also Regents of the Univ. of Minn. v. Aga Medical Corp.*, 717 F.3d 929, 943-44 (Fed. Cir. 2013). Thus, that these statements were made during prosecution of the '474 patent rather than the '283 or '608 patent is of no moment; these were global statements directed to the invention generally. The "distinct bead" limitations of the later patents are substantially similar to the "distinct component" limitation of the '474 patent, and thus properly inform the construction here. *See, e.g., Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1314 (Fed. Cir. 2007) (applying statements from prosecution of a familial patent to overcome prior art in construing claims relating to the same subject matter).

Having represented the scope of its invention as limited to formulations where the carboxylic acid is in a separate bead, the onus was on Impax to inform the examiner if they intended to rescind this disclaimer in subsequent applications. *See Hakim v. Cannon Avent Grp., PLC*, 479 F.3d 1313, 1318 (Fed. Cir. 2007) ("[T]he prosecution history must be sufficiently clear to inform the examiner that the previous disclaimer, and the prior art that it was made to avoid, may need to be revisited."). The applicants never did so. In fact, the examiner's comments in allowing the claims of the '608 patent confirm that the claims were continually understood as limited to formulations having a separate carboxylic acid bead:

> ***The novelty of the instant composition resides on the fact that the carboxylic acid are in a [sic] separate beads.*** Such acid is used in the prior art as excipients such as pH adjusting agents. However, the encapsulation of the carboxylic acid (***i.e., in beads separated from the other two active components – levodopa and carbidopa***) would generate a superior releasing profile. These effects are not taught or fairly suggested by the prior art.

(Ex. 12, '608 File History at IMPAX00313882.) Therefore, the Court's analysis as to the term "distinct component" applies equally to the term "distinct bead" in dispute here.

Impax's interpretation of "distinct bead" flies in the face of common sense, the intrinsic record, and the Court's previous claim construction ruling. The Court should reject this blatant attempt by Impax to manufacture an infringement argument where none exists and instead adopt Actavis's claim construction, which is consistent with the plain meaning of the term, the intrinsic

record, and the Court's previous claim construction findings in this case.

B. Actavis's Products Cannot Literally Infringe the Asserted Claims that Require a Carboxylic Acid in a "Distinct Bead"

With respect to the "distinct bead" limitations, the asserted claims of the '283 and '608 patents are substantially similar and Actavis's Products do not infringe them all for the same reason. Each of the claims requires a controlled release formulation of CD/LD that contains carboxylic acid, "wherein the carboxylic acid of (c) is in a distinct bead from [CD/LD]."

There is no dispute regarding the formulation or architecture of Actavis's Products.

[redacted]

For the reasons set forth above, the Court should reject Impax's strained reading of the claims, and construe the phrase "wherein the carboxylic acid of (c) is in a distinct bead from (a) or (b)" to require that the carboxylic acid be included in a bead that contains no CD/LD. Under this construction, there is no dispute that Actavis's Products would not literally infringe the asserted claims of the '283 and '608 patents.

C. Actavis's Products Cannot Infringe the Asserted Claims that Require a Carboxylic Acid in a "Distinct Bead" under the Doctrine of Equivalents

Impax also argues that Actavis's Products infringe the claims under the doctrine of equivalents [redacted] But as the Court has already recognized, Impax is estopped from recapturing claim scope that it surrendered to circumvent the prior art and obtain the patents-in-suit.

Prosecution history estoppel is a legal limitation on the scope of the doctrine of equivalents. *Biagro W. Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1301-02 (Fed. Cir. 2005). "[T]he application and scope of prosecution history estoppel, including whether the presumption of surrender of subject matter has arisen and whether it has been rebutted, are questions of law to be decided by the court." *Id.* A patentee's argument in rebuttal of the presumption may be subject to underlying factual issues, which may properly be decided by the court. *Id.*

Under the doctrine of the equivalents, "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements

of the patented invention." *Warner–Jenkinson*, 520 U.S. at 21. However, the doctrine of prosecution history estoppel prevents a patent owner from recapturing through the doctrine of equivalents subject matter surrendered to acquire the patent. *See Festo*, 535 U.S. at 734.

The Court has already recognized that, in order to obtain allowance of the asserted claims of the '474 patent, Impax specifically disclaimed all formulations where the carboxylic acid was not in a separate component from the active ingredients. (D.I. 118 at 26.) Specifically, Impax amended its claims and distinguished its claimed formulation over Nangia. (Ex. 11, '474 File History at IMPAX00312304-333.) These arguments distinguishing its invention from the prior art limit the application of the doctrine of equivalents for the claims of the '283 and '608 patents, which each claim priority to the '474 patent. *See, e.g, Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 981 (Fed. Cir. 1999) (using statements made in prosecuting parent application to preclude application of doctrine of equivalents for similar claims in child patent). The Examiner in fact expressly recognized the disclaimer when allowing the '608 patent claims, stating that "[t]he novelty of the instant composition resides on the fact that the carboxylic acid are in a [sic] separate beads." (Ex. 12, '608 File History at IMPAX00313882.)

Having disavowed the claim scope by distinguishing prior art, Impax cannot now recapture that scope through the doctrine of equivalents. As discussed above, Impax repeatedly distinguished the prior art during prosecution by emphasizing that, while the prior art formulations had the carboxylic acid, levodopa, and carbidopa "present in a single particle or bead," its alleged invention was premised on the discovery of the need to "create a separate carboxylic acid bead in the multiparticulate formulation." (Ex. 11, '474 File History at IMPAX00312254.) Having surrendered the claim scope to secure its patents, the Court should not allow Impax to recapture it now. Actavis has a right to rely on the assertions made by Impax

to secure allowance of the claims. *See Desper Products, Inc. v. QSound Labs, Inc.*, 157 F.3d 1325, 1340 (Fed. Cir. 1998) ("Post-hoc, litigation-inspired argument cannot be used to reclaim subject matter that the public record in the PTO clearly shows has been abandoned."). Consistent with its prior ruling, the Court should hold that Impax is estopped from relying on the doctrine of equivalents to recapture claim scope that it surrendered during prosecution of the patents-in-suit.

V. ACTAVIS'S PRODUCTS WILL NOT INFRINGE ANY OF THE ASSERTED CLAIMS REQUIRING SPECIFIC PHARMACOKINETIC PROFILES

As discussed above, Actavis will not administer its Products to patients and therefore cannot be liable for direct infringement. In order to prove that Actavis indirectly infringes any of the method of use claims, Impax must prove that Actavis induces or contributes to an act of direct infringement. *See Limelight*, 134 S. Ct. at 2117. Administration of Actavis's Products will not directly infringe any of the claims directed to specific PK profiles, and as such Actavis cannot be liable for indirect infringement.

A. Claim Construction

The dispute over whether Actavis's Products will meet the PK profile claim limitations of the '246, '046 and '608 patents involves claim construction, with the operative facts undisputed. The first term at issue is "the maximum concentration of said profile" and the second term is "the levodopa blood plasma levels do not fluctuate more than 40% between 0.5 hours and six hours after administration."

Each of the PK profile claim limitations requires either that the product have a particular LD plasma concentration profile, or that the patient have a particular LD plasma concentration profile following administration of the product. Following administration of a drug product containing LD, the concentration of LD in the blood increases as the LD is absorbed and then

decreases as the LD is eliminated. A LD plasma concentration profile describes the relationship between the concentration of LD in the blood plasma over time.

1. "maximum concentration"

Claim 21 of the '608 patent, and all of the asserted claims of the '246 and '046 patents require that the LD plasma concentration profile have certain characteristics. Among these is the requirement that the profile have "a second concentration at a second time" where "said second concentration is equal to the maximum concentration of said profile."[5]

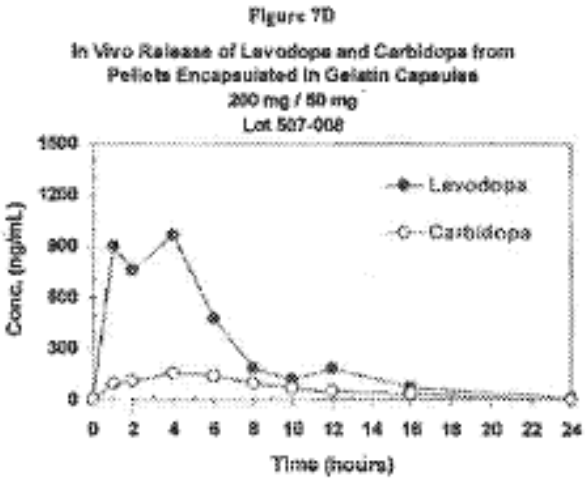
Notably, the parties previously agreed that the phrase, "said second concentration is equal to the maximum concentration of said profile" requires no construction and should be given its plain and ordinary meaning. (D.I. 56.) The plain and ordinary meaning of "maximum concentration of said profile" unquestionably refers to the highest concentration of the profile.

[redacted] The Court should reject Impax's attempt to backtrack from its prior agreement and proffer a new construction for this term.

[5] This language is reproduced from claim 21 of the '608 patent. The claims of the '246 and '046 patent use substantially similar, although not identical language. For example, the asserted claims of the '246 and '046 patents refer to "a second concentration that occurs at a second time" and states that "the second concentration is the maximum concentration of levodopa in the profile." The relevant term, "maximum concentration," appears in all of these claims. Thus, these terms should be construed to have the same meaning in all three patents. *See NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1293 (Fed. Cir. 2005) (stating that where multiple patents "derive from the same parent application and share many common terms, we must interpret the claims consistently across all asserted patents.").

The intrinsic evidence is entirely consistent with "maximum concentration" referring to the highest concentration in the profile, not the first peak in the profile. For example, the common specification repeatedly equates "maximum plasma concentration" with C_{max}, which refers to the highest plasma concentration, regardless of whether it happens to be the first peak in the profile. (Ex. 2 at 13:9, 17:20, 21:24.) This understanding is confirmed by U.S. Patent No. 7,094,427 ("the '427 patent").[6] The '427 patent explains that "[i]nitial peak plasma level refers to the first rise in blood plasma level of active agent and may be followed by one or more additional peaks, one of which may be C_{max}." (Ex. 6, '427 patent at 4:25-27.) Thus, a POSA would have understood that C_{max}, or maximum plasma concentration, does not refer to the first peak in a profile.

Furthermore, during prosecution of the '246 patent, Impax interpreted "maximum plasma concentration" to mean the highest concentration in order to distinguish its claims from a prior art reference. (*See* Ex. 13, '246 File History at IMPAX00852513-14.) The profile reported in that prior art reference is reproduced below.



[6] The '427 patent is another one of the Orange Book listed patents for Rytary® and has been asserted by Impax in this case. Impax's claims related to the '427 patent have been stayed pending reexamination. (D.I. 47.)

In distinguishing this profile from its claims, Impax explained that the claims required a second concentration that is the "maximum plasma concentration (C_{max}) of the drug" and a third concentration that is 50% to 60% of "the maximum plasma concentration (C_{max})" at least 4 hours after the second concentration. (*Id*.) Impax contended that the prior art profile did not meet these limitations because the second concentration was 966.3 ng/ml at 4 hours, and the concentration was below 50% of this concentration by 8 hours (*i.e.*, 4 hours later). (*Id*.) As can be seen from the figure, had Impax considered "the maximum concentration" to refer to the first peak rather than the highest concentration, the "maximum concentration" would have been 900 ng/ml at 1 hour, and there would have been a third concentration between 50% and 60% of the maximum at least 4 hours later (*i.e.*, at 5 hours or later). Having interpreted the term "maximum concentration" to refer to the highest concentration in order to overcome prior art during prosecution, Impax cannot now change its position to salvage its infringement claims. *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995) ("Claims may not be construed one way in order to obtain their allowance and in a different way against accused infringers."). The Court should therefore construe "maximum concentration" in accordance with its plain and ordinary meaning to refer to the highest concentration in the profile.

2. 40% Fluctuation

Claims 26, 37, 40, 42, 44, and 48 of the '246 patent and all of the asserted claims of the '046 patent require that "the levodopa blood plasma levels do not fluctuate more than 40% between 0.5 hours and six hours after administration." While this term undoubtedly requires the LD concentration to remain within ±40% of some LD concentration between 0.5 and 6 hours, it is unclear which LD concentration should be used to calculate the 40% fluctuation range. More specifically, a POSA would not know from the claim language alone whether the 40% range should be calculated based on the concentration at 0.5 hours, 6 hours, or some point in between,

e.g., C_{max}. (Jenner Decl., Ex. B at ¶¶ 17-19.) Depending upon which concentration is used to calculate the 40% fluctuation range, the range may differ substantially. (*Id.* at ¶ 20.)

Although the specification does not inform a POSA how the 40% fluctuation range should be calculated, the prosecution history provides guidance. To overcome a rejection during prosecution of the '246 patent, Impax asserted that the LD plasma concentration profile reported in the prior art did not meet this limitation. (*See* Ex. 13, '246 File History at IMPAX00852514-15.) To support this position, Impax calculated the 40% fluctuation range based on both the 0.5 and 6-hour concentrations, and asserted that because the highest concentration of the prior art profile was outside these ranges, the prior art profile did not meet the limitation. (*See id.*) Impax again considered both the 0.5-hour and 6-hour time points in determining whether this limitation was satisfied by the prior art during prosecution of the '046 patent. (*See* Ex. 14, '046 File History at IMPAX00852811.)

Calculating the 40% fluctuation range using both the 0.5-hour and 6-hour time points and requiring the concentration to stay within both ranges between 0.5 and 6 hours is therefore consistent with the prosecution history. Particularly in the absence of a specific directive to select one or the other points to calculate the fluctuation range, a POSA would understand that administration of a formulation only meets this limitation if the LD plasma concentrations stay within the range of ±40% of the concentrations at both the 0.5-hour and 6-hour time points.

B. Impax's Infringement Allegations Ignore the Actual "Maximum Concentration" of Actavis's Levodopa Concentration Profiles

1. Actavis's Products Will Not Infringe Claim 21 of the '608 Patent

(a) Literal Infringement

Claim 21 of the '608 patent requires that the formulation have a median plasma concentration profile comprising, "a second concentration at a second time" wherein "said

second concentration is equal to the maximum concentration of said profile.” Claim 21 also requires “a third concentration at a third time, that occurs at least four hours after said second time” wherein “said third concentration is equal to about fifty percent of said second concentration.” [redacted]

[redacted]

[redacted]

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[7] While Actavis maintains that this claim is indefinite because the profile obtained when a formulation is administered depends on a variety of factors, and thus a formulation does not “have” a profile, for purposes of this motion Actavis assumes the claim is definite.

[redacted].

[redacted]

[redacted] For the reasons set forth above, the Court should adopt Actavis's claim construction and find that Actavis's Products will not infringe claim 21 of the '608 patent.

(b) Doctrine of Equivalents

There is also no evidence that Actavis's Products will infringe claim 21 under the doctrine of equivalents. [redacted]

2. Administration of Actavis's Products Will Not Directly Infringe Claims 1, 9, 14, 17, 19, 21, 25, 49, 51, and 53 of the '246 Patent or Claims 7, 12, 14, 16, 18, and 31 of the '046 Patent

(a) Literal Infringement

Like claim 21 of the '608 patent, independent claims 1 and 51 of the '246 patent and independent claims 1 and 23 of the '046 patent (and both patents asserted dependent claims[8]) require a levodopa plasma concentration profile comprising "a second concentration that occurs at a second time" wherein "the second concentration is the maximum concentration of levodopa in the profile," as well as "a third concentration that occurs after said second concentration and at a third time that is at least four hours after said second concentration." The '246 claims require that "said third concentration is about fifty percent to about sixty percent of the second concentration" while the '046 claims require that "the peak-to-trough ratio of the second concentration to the third concentration is about 1.5 to 2.5."[9]

[redacted]

[8] In the text of this section, the relevant asserted independent claims are discussed. The conclusions apply to each of the asserted claims that depend on the recited independent claims.

[9] Unlike claim 21 of the '608 patent, these claims are directed not to the product itself, but rather to a method of administering the product. And the profile is not the median LD concentration profile, but rather "***the patient's*** levodopa plasma concentration profile." (*E.g.*, Ex. 3, 246 patent at claim 1; Ex. 4, '046 patent at claim 1.)

[10] While Actavis maintains that these claims are indefinite because the profile obtained when a formulation is administered depends on a variety of factors, and thus a formulation does not "comprise" a profile, for purposes of this motion Actavis assumes these claims are definite.

[redacted]

These claims also require "a third concentration that occurs after said second concentration and at a third time that is at least four hours after said second concentration." The '246 claims require that "said third concentration is about fifty percent to about sixty percent of the second concentration" while the '046 claims require that "the peak-to-trough ratio of the second concentration to the third concentration is about 1.5 to 2.5." [redacted]

[redacted] Accordingly, Actavis's Products will not literally infringe claims 1 or 51 of the '246 patent or claims 1 or 23 of the '046 patent (or any claim that depends from these claims).

[redacted]

[redacted] For the same reasons as discussed with respect to claim 21 the '608 patent, the Court should find that administration of Actavis's Products will not infringe claim 1 or 51 of the '246 patent or claim 1 or 23 of the '046 patent (or any claim that depends from these claims).

Claims 9, 14, 17, 19, 21, 25, and 49 depend from claim 1 and claim 53 depends from claim 51 of the '246 patent. Claims 7, 12, 14, 16, 18 depend from claim 1 and claim 31 depends from claim 23 of the '046 patent. The administration of Actavis's Products would therefore not infringe these dependent claims for the same reasons as set forth with respect to claims 1 and 51 of the '246 patent and claims 1 and 23 of the '046 patent.

(b) Doctrine of Equivalents

Nor is there any evidence that administration of Actavis's Products will infringe claim 1 or 51 of the '246 patent or claim 1 or 23 of the '046 patent, or their asserted dependent claims, under the doctrine of equivalents. To establish infringement under the doctrine of equivalents, Impax would need to prove that administration of Actavis's Products will lead to a LD concentration profile with an equivalent to "a third concentration that occurs after said second concentration and at a third time that is at least four hours after said second concentration" wherein "said third concentration is about fifty percent to about sixty percent of the second concentration" or "the peak-to-trough ratio of the second concentration to the third concentration is about 1.5 to about 2.5," where the second concentration occurs at 4.5 hours. [redacted]

[redacted]

C. Administration of Actavis's Products Will Not Directly Infringe Those Claims of the '246 and '046 Patents That Require No More Than 40% Fluctuation

1. Literal Infringement

Each of claims 26, 37, 40, 42, 44, and 48 of the '246 patent and all asserted claims of the '046 patent require administration of a formulation such that "following a single dose administration of the multiparticulate formulation the LD blood plasma levels do not fluctuate more than 40% between 0.5 hours and six hours after administration." [redacted]

[redacted]

Therefore, administration of Actavis's Products will not literally infringe claim 26 of the '246 patent or any asserted claim of the '046 patent, or those claims dependent thereon.

[redacted]

2. Doctrine of Equivalents

There is also no evidence that administration of Actavis's Products will infringe claim 26 the '246 patent or any asserted claim of the '046 patent under the doctrine of equivalents. To establish infringement under the doctrine of equivalents, Impax would need to prove that administration of Actavis's Products will lead to a LD concentration profile with an equivalent to "levodopa blood plasma levels do not fluctuate more than 40% between 0.5 hours and six hours after administration." [redacted]

[redacted]

Claims 37, 40, 42, 44, and 48 depend from claim 26 of the ’246 patent, and all asserted claims of the ’046 patent include the 40% fluctuation limitation. These claims would therefore not be infringed by administration of Actavis’s Products for the same reasons.

D. Actavis Will Not Induce or Contribute to Infringement of Any of the Asserted Claims of the ’246 or ’046 Patents

Even if Impax is correct that the mean LD plasma concentration profiles associated with Actavis’s fasted clinical studies meet the limitations of the claims of the ’246 and ’046 patents, Impax still cannot show that Actavis will induce or contribute to infringement of any of these claims, and for this additional reason, summary judgment should be granted in Actavis’ favor.

In order to prove inducement, Impax must show, “first that there has been direct infringement, and second that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement.” *Minnesota Min. & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1304–05 (Fed. Cir. 2002). In contrast to direct infringement, liability for inducement attaches only if the defendant knew of the patent and that “the induced acts constitute patent infringement.” *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1926 (2015). There is no evidence that Actavis possessed the specific intent to induce infringement of the claims of the ’246 or ’046 patents.

Each of the claims of the ’246 and ’046 patents require that following administration, “***the patient’s*** levodopa plasma concentration profile comprises” the recited profile. [redacted]

[redacted]

[redacted] As this Court explained in an essentially identical situation,

> [t]he problem is that the statement that the medication may be taken with or without food cannot be reasonably understood to be an instruction to engage in an infringing use. As Defendants contend, it is indifferent to which option is selected. At most, it may be understood to permit an infringing use, but permission is different from encouragement.

Shire LLC v. Amneal Pharm., LLC, C.A. No. 11-3781 (SRC), 2014 WL 2861430, at *5 (D.N.J. June 23, 2014), *aff'd in part, rev'd in part and remanded*, 802 F.3d 1301 (Fed. Cir. 2015). [redacted]

[redacted].

With regard to contributory infringement, Impax alleges that Actavis's Products are especially made for use in an infringing way. However, as just discussed, Actavis's Products have substantial non-infringing uses—[redacted]

Accordingly, Actavis will not induce infringement or contribute to infringement of any of the asserted claims of the '246 or '046 patents.

VI. CONCLUSION

For the foregoing reasons, Actavis respectfully request its motion be granted.

Dated: October 23, 2017

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